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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Patent Application of: Joanne Y. H. Kwak-Kim et al.
For: DIAGNOSIS AND TREATMENT OF INFERTILITY
Serial No. 10/651,690
Filed: August 28, 2003
Examiner: Michael E. Szperka
Art Unit: 1644
Conf. No. 9043

VIA FACSIMILE

I hereby certify that this paper is being facsimiled to the United States Patent and Trademark Office facsimile no.: (571) 273-8300 on December 26, 2007.

Tammy Prusa

PETITION UNDER 37 C.F.R. §1.183 TO SUSPEND THE RULES REQUIRING THE SIGNATURE OF ALL INVENTORS FOR A DECLARATION OF COMBINED JOINT INVENTORSHIP UNDER 37 C.F.R. §1.131

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to Examiner's request Applicants respectfully petition to suspend the rules requiring the signatures of all inventors for a declaration of combined joint inventorship under 37 C.F.R. §1.131 for the above-named application. Joint inventor Alan E. Beer is deceased, and is therefore unavailable to sign the declaration under 37 C.F.R. §1.131. Applicants submit herewith, the necessary petition fees set forth in §1.17(f). Applicants request Examiner to contact the Attorney of Record if any further questions arise in connection with this petition.

Respectfully submitted,

Date: December 26, 2007

BY _____
Joseph A. Fuchs, Reg. No. 34,604
Rockey Depke Lyons, LLC
Suite 5450 Sears Tower
233 S. Wacker Drive
Chicago, IL 60606-6306
312-277-2006 (main)
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12/28/2007 HDESTA1 00000033 503891 10651690
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PTO/SB/17p (12-07)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PETITION FEE
Under 37 CFR 1.17(f), (g) & (h)
TRANSMITTAL

(Fees are subject to annual revision)

Send completed form to: Commissioner for Patents
P.O. Box 1450, Alexandria, VA 22313-1450

Application Number	10/651,690
Filing Date	August 28, 2003
First Named Inventor	Joanne Kim
Art Unit	1644
Examiner Name	Michael Edward Szperka
Attorney Docket Number	112461.00016

Enclosed is a petition filed under 37 CFR 1.183 **that requires a processing fee (37 CFR 1.17(f), (g), or (h)). Payment of $** 400.00 **is enclosed.**

This form should be included with the above-mentioned petition and faxed or mailed to the Office using the appropriate Mail Stop (e.g., Mail Stop Petition), if applicable. *For transmittal of processing fees under 37 CFR 1.17(i), see form PTO/SB/17i.*

Payment of Fees (small entity amounts are NOT available for the petition fees)

☑ The Commissioner is hereby authorized to charge the following fees to Deposit Account No. 50-3891 :

☐ petition fee under 37 CFR 1.17(f), (g) or (h) ☐ any deficiency of fees and credit of any overpayments

Enclose a duplicative copy of this form for fee processing.

☐ Check in the amount of $_____ is enclosed.

☐ Payment by credit card (Form PTO-2038 or equivalent enclosed). Do not provide credit card information on this form.

Petition Fees under 37 CFR 1.17(f): Fee $400 Fee Code 1462

For petitions filed under:
§ 1.36(a) - for revocation of a power of attorney by fewer than all applicants
§ 1.53(e) - to accord a filing date.
§ 1.57(a) - to accord a filing date.
§ 1.182 - for decision on a question not specifically provided for.
§ 1.183 - to suspend the rules.
§ 1.378(e) - for reconsideration of decision on petition refusing to accept delayed payment of maintenance fee in an expired patent.
§ 1.741(b) - to accord a filing date to an application under § 1.740 for extension of a patent term.

Petition Fees under 37 CFR 1.17(g): Fee $200 Fee Code 1463

For petitions filed under:
§ 1.12 - for access to an assignment record.
§ 1.14 - for access to an application.
§ 1.47 - for filing by other than all the inventors or a person not the inventor.
§ 1.59 - for expungement of information.
§ 1.103(a) - to suspend action in an application.
§ 1.136(b) - for review of a request for extension of time when the provisions of section 1.136(a) are not available.
§ 1.295 - for review of refusal to publish a statutory invention registration.
§ 1.296 - to withdraw a request for publication of a statutory invention registration filed on or after the date the notice of intent to publish issued.
§ 1.377 - for review of decision refusing to accept and record payment of a maintenance fee filed prior to expiration of a patent.
§ 1.550(c) - for patent owner requests for extension of time in ex parte reexamination proceedings.
§ 1.956 - for patent owner requests for extension of time in inter partes reexamination proceedings.
§ 5.12 - for expedited handling of a foreign filing license.
§ 5.15 - for changing the scope of a license.
§ 5.25 - for retroactive license.

Petition Fees under 37 CFR 1.17(h): Fee $130 Fee Code 1464

For petitions filed under:
§ 1.19(g) - to request documents in a form other than that provided in this part.
§ 1.84 - for accepting color drawings or photographs.
§ 1.91 - for entry of a model or exhibit.
§ 1.102(d) - to make an application special.
§ 1.138(c) - to expressly abandon an application to avoid publication.
§ 1.313 - to withdraw an application from issue.
§ 1.314 - to defer issuance of a patent.

Joseph Fuchs
Signature

December 26, 2007
Date

Joseph A. Fuchs
Typed or printed name

34,604
Registration No., if applicable

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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Tammy Prusa

SUPPLEMENTAL DECLARATION OF COMBINED JOINT INVENTORS UNDER 37 C.F.R. §1.131

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Joanne Young Hee Kwak-Kim, M.D. and Alice Gilman-Sachs, Ph.D. aver as follows:

1. We are over the age of twenty-one years and make these statements from our own personal knowledge.

2. I, Dr. Kwak-Kim currently hold the position of the Assistant Chair, Department of Obstetrics and Gynecology; and the Medical Director, the Clinics at Rosalind Franklin University of Medicine and Science; and the Director, Women's Health Division, University Clinics; and Associate Professor, Department of Obstetrics and Gynecology and the Department of Microbiology and Immunology of the Rosalind Franklin University of Medicine and Science (formerly known as Finch University of Health Sciences) / The Chicago Medical School.

3. I, Dr. Gilman-Sachs, currently hold the position of Associate Professor of the Rosalind Franklin University of Medicine and Science (RFUMS) and also hold the position of Associate Director Clinical Immunology Laboratory for RFUMS.

4. We are both joint inventors of the above-captioned patent application.

5. Joint inventor Alan E. Beer is deceased.

6. Prior to April 19, 1999 we planned to study the affect on reproductive outcomes, in subjects with a history of recurrent spontaneous abortions or implantation failures, by adjusting the balance of T helper (Th1) and T helper 2 (Th2) immune responses in the subject. A letter signed by Dr. Kwak-Kim with the date expurgated is attached as Exhibit 1 and was mailed prior to the Critical Date. In particular, we determined to decrease the ratio of Th1 immune response to Th2 immune response by either (a) down regulating the Th1 immune response, (b) by up regulating the Th2 immune response or (c) by both down regulating the Th1 immune response while up regulating the Th2 response.

7. Further to this planned study, prior to the Critical Date we began development of an assay to measure the ratio of Th1 to Th2 immune responses in a subject. We have attached as Exhibit 2 a set of laboratory notebook pages with dates removed evidencing the development of the assay. The ratio of the Th1 to Th2 immune responses can be measured by absolute cell counts or percentages of Th1 to Th2 cells. The Th1 cells are activated T-cells expressing Th1 cytokines such as IL-1, IL-2, IFN-γ and TNF-α. Th2 cells are activated T-cells expressing Th2 cytokines such as IL-4, IL-5, IL-6 and IL-10. The ratio of the Th1 to Th2 immune responses can also be determined by calculating a ratio of any one of the Th1 cytokines to any one of the Th2 cytokines.

8. One method we contemplated to reduce the Th1 count was to administer to a subject, prior to conception by the subject, a TNF- α antagonist. TNF- α antagonist may be of several types including antibodies, soluble receptors, and chemical compounds. We contemplated using several commercially available TNF- α antagonists and TNF- α antagonists that were undergoing an FDA approval process in the hope of becoming commercially saleable. Examples of antibody type and soluble receptor-type TNF- α antagonists included, but were not limited to: (1) infliximab (antibody-type) (2) entanercept (soluble receptor-type) (See Exhibit 1), (3) D2E7 (antibody-type) (4) CDP571 (anti-body type) and (5) CDP870 (anti-body type).

9. We contemplated administering the TNF- α antagonist by any medically suitable route of administration.

10. Accordingly, at the time of conception we contemplated in vivo methods of treatments.

11. After conceiving of these concepts we worked on them diligently from prior to the Critical Date up to the time of filing the above-captioned patent application.

12. Evidence of successful in vivo applications is provided in the specification of the above-captioned application.

13. All of the work we have referred to herein was done in the United States of America.

14. All of the work we have referred to herein, including the set of laboratory notebook pages (Exhibit 2) was a result of our combined collaborations. Although the term "I" is used in the letter from Dr. Kwak-Kim to Wyeth-Ayerst Laboratories (Exhibit 1), we believe that conception of the above-captioned patent application was a collaborative effort by the named inventors. The term "I" was used in Exhibit 1 because Dr. Kwak-Kim was the primary contact with Wyeth-Ayerst Laboratories.

I hereby declare that all statement made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further, I acknowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and may jeopardize the validity of the application or any patent issuing thereon.

Date: 12/20/07 BY: Alice Sachs (Gilman-Sachs)

Date: _____ BY: _____

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Date: 12/19/2007 BY: _____

Date: _____ BY: _____

Assisted Reproductive Technology: Home

Infertility is often defined as not being able to get pregnant after trying for one year. Of the approximately 62 million women of reproductive age in 2002, about 1.2 million, or 2%, had an infertility-related medical appointment within the previous year, and 10% had an infertility-related medical visit at some point in the past. (Infertility services include medical tests to diagnose infertility, medical advice and treatments to help a woman become pregnant, and services other than routine prenatal care to prevent miscarriage.) Additionally, 7% of married couples in which the woman was of reproductive age (2.1 million couples) reported that they had not used contraception for 12 months and the woman had not become pregnant (2002 National Survey of Family Growth).

Thus, for many people who want to start a family, the dream of having a child is not easily realized. Assisted Reproductive Technology (ART) has been used in the United States since 1981 to help women become pregnant, most commonly through the transfer of fertilized human eggs into a woman's uterus (**in vitro fertilization**). However, deciding whether to undergo this expensive and time-consuming treatment can be difficult.

What is Assisted Reproductive Technology (ART)?

Although various definitions have been used for ART, the definition used by CDC is based on the 1992 Fertility Clinic Success Rate and Certification Act that requires CDC to publish the annual *ART success rates report*. According to this definition, ART includes all fertility treatments in which both eggs and sperm are handled. In general, ART procedures involve surgically removing eggs from a woman's ovaries, combining them with sperm in the laboratory, and returning them to the woman's body or donating them to another woman. They do NOT include treatments in which only sperm are handled (i.e., intrauterine—or artificial—insemination) or procedures in which a woman takes medicine only to stimulate egg production without the intention of having eggs retrieved.

The goal of this report is to help potential ART users make informed decisions about ART by providing some of the information needed to answer the following questions:

What are my chances of having a child by using ART?
Where can I go to get this treatment?

Selected Resources

Preliminary 2005 Fertility Clinic Success Rates and National Summary†

This report from the Centers for Disease Control and Prevention's Division of Reproductive Health includes:

- Fertility clinic tables on the types of assisted reproductive technology (ART) used, patient diagnoses, success rates that each clinic reported, and individual program characteristics.
- A national summary table based on data from all reporting fertility clinics.

†The findings represent data from 422 fertility clinics in operation in 2005. The 134,242 ART cycles performed at these reporting clinics resulted in 38,910 live births (deliveries of one or more living infants) and 52,041 infants. This information is preliminary and subject to change until the final report publication, tentatively scheduled to be released December 2007. CDC assumes no liability for the completeness or accuracy of the data and cannot be held responsible for using the preliminary data.

Assisted Repr Technology (A

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ART Success R National Summ Fertility Clinic R

2005 Preliminary Success Rates

2004 ART Repor

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- Adolescent Reproductive H
- Assisted Repro Technology
- Global Reprod Health
- Maternal and I Health
- Refugee Repro Health
- Sudden Infant Syndrome
- Unintended Pr
- Women's Repr Health

- Division of Rep Health

Contact Info

CDC/DRH
4770 Buford Hwy.
MS K-20
Atlanta, GA 3034

Phone number

770-488-5200

› Contact Us

2004 Assisted Reproductive Technology Success Rates
National Summary and Fertility Clinic Reports

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The 2004 report of pregnancy success rates is the tenth report to be issued under the Fertility Clinic Success Rate and Certification Act. The report includes a national overview that uses information from 411 U.S. fertility clinics to provide an in-depth picture of the type, number, and outcome of ART cycles performed in U.S. clinics. The report also includes individual clinic tables that provide ART success rates and other information from each clinic that submitted and verified its 2004 data and appendixes containing the results of data validation visits, technical notes, a glossary, and contact information for reporting and nonreporting clinics in the United States.

Previous ART Reports

2003 | 2002 | 2001 | 2000–1995 (PDF format only)

Excel Spreadsheets of the ART clinic data

2004 | 2003 | 2002 | 2001 | 2000 | 1999 | 1998 | 1997 | 1996 | 1995

Assisted Reproductive Technology Surveillance—United States, 2004
This supplemental surveillance report includes detailed statistics from the Assisted Reproductive Technology (ART) Surveillance System by state of residency. The report expands information on geography and determinants of ART success and the risks associated with ART (e.g., multiple births, low birthweight, and preterm delivery) beyond what appears in the *2004 Assisted Reproductive Technology Success Rates: National Summary and Fertility Clinic Report.* Source: *MMWR* 2007;56 (No. SS-6) 1–22

Previous ART Surveillance Summary
2003 | 2002 | 2001 | 2000

Increasing infant mortality among very low birthweight infants — Delaware, 1994–2000.
Source: *MMWR* 2003;52:862–866.

Use of Assisted Reproductive Technology—United States, 1996 and 1998
Since 1983, when the first infant was conceived from in vitro fertilization (IVF) in the United States, the use of IVF and related procedures (assisted reproductive technology) has increased substantially. Source: *MMWR* 2002;51(05):97–101.

Contribution of Assisted Reproductive Technology and Ovulation-Inducing Drugs to Triplet and Higher-Order Multiple Births— United States, 1980–1997
Pregnancies associated with assisted reproductive technology (ART) and drugs that induce ovulation are more likely to result in multiple births than spontaneously conceived pregnancies in the United States. Source: *MMWR* 2000;49(24):535–538.

Impact of Multiple Births on Low Birthweight - Massachusetts, 1989-1996.
Source: *MMWR* 1999;48(14):289–292.

Reporting of Pregnancy Success Rates from Assisted Reproductive Technology Programs* (PDF 540KB) This notice was published in the *Federal Register*, Tuesday, February 1, 2005. It provides information for clinics that report data for publication in *Assisted Reproductive Technology Success Rates: National Summary and Fertility Clinic Reports.*

Related Resources

Division of Reproductive Health's ART Surveillance System
In the U.S. and worldwide, assisted reproductive technologies (ARTs) are increasingly used to overcome all types of infertility disorders. More than 49,000 infants were born from ART treatments in 2004, representing more than 1% of the U.S ...more

Infertility FAQ's (National Women's Health Information Center)

How Do I Know If I Have an Infertility Problem?* (Resolve: The National Infertility Association)

Infertility (March of Dimes)*

American Fertility Association*
The American Fertility Association (AFA) is a national consumer organization that offers support for men and women dealing with infertility. Their purpose is to educate the public about reproductive disease, and support families during struggles with infertility and adoption.

Fertile Hope*
Fertile Hope is a national nonprofit organization dedicated to providing reproductive information, support and hope to cancer patients whose medical treatments present the risk of infertility.

American Society for Reproductive Medicine*
The American Society for Reproductive Medicine (ASRM) is a multidisciplinary organization for the advancement of information, education, advocacy and standards in the field of reproductive medicine.

RESOLVE: The National Infertility Association*
RESOLVE is a national consumer organization that offers support for men and women dealing with infertility. Their purpose is to provide timely, compassionate support and information to people who are experiencing infertility and to increase awareness of infertility issues through public education and advocacy.

Society for Assisted Reproductive Technology*
The Society for Assisted Reproductive Technology (SART) promotes and advances the standards for the practice of assisted reproductive technology to the benefit of patients, members and society at large.

Tissue Action Plan (FDA)
The purpose of the Tissue Action Plan is to develop the policies, regulations and guidance documents for regulation of cellular and tissue-based products ...more

Human Cell, Tissues and Cellular and Tissue-Based Products (FDA)
Listing of ART clinics registered with FDA.

Implementation of the Fertility Clinic Success Rate and Certification Act of 1992: A Model Program for the Certification of Embryo Laboratories
This notice sets forth the model certification program requirements, including definitions, administrative requirements, and embryo laboratory standards. The model program incorporates comments received by CDC on the proposed model certification program that was published in the Federal

Assisted Reproductive Technology: Embryo Laboratory PDF 435KB
This site links to the (1) January 1999 report entitled Survey of Assisted Reproductive Technology: Embryo Laboratory Procedures and Practices (119 pages); and (2) Proposed Model Certification Program for Embryo Laboratories as required by the Fertility Clinic Success Rate and Certification Act of 1992.

Search PubMed for articles on Assisted Reproductive Technology
This search is being conducted on PubMed an NLM/NIH service.

* Links to non-Federal organizations found at this site are provided solely as a service to our users. These links do not constitute an endorsement of these organizations or their programs by CDC or the Federal Government, and none should be inferred. The CDC is not responsible for the content of the individual organization Web pages found at these links.

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Page last reviewed: 7/19/07

Page last modified: 6/6/07
Content source: Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion

SAFER • HEALTHIER • PEOPLE™
Centers for Disease Control and Prevention, 1600 Clifton Rd. Atlanta, GA 30333, U.S.A
Tel: (404) 639-3311 / Public Inquiries: (404) 639-3534 / (800) 311-3435